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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,951	03/01/2006	Paul William Richard Harris	NRNZ-01048US1	1343

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EXAMINER	
JARRELL, NOBLE E	

ART UNIT	PAPER NUMBER
1624	

MAIL DATE	DELIVERY MODE
09/05/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/549,951	HARRIS ET AL.	
	Examiner	Art Unit	
	NOBLE JARRELL	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,9,11-14,16,18,23,30,31 and 35-63* is/are pending in the application.

4a) Of the above claim(s) *1-2,9,11-14,16,18,23,30-31 and 35-45* is/are withdrawn from consideration.

5)☒ Claim(s) *46-50* is/are allowed.

6)☒ Claim(s) *51-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 September 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/21/2007;6/9/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. As a result of applicant's amendments, claims 1-2,9,11-14,16,18,23,30-31,and 35-45 are now withdrawn. Claims 46-63 are being acted on in this action.

2. The rejection under 35 U.S.C. 112 2nd paragraph has been overcome by the amendment filed 6/9/2008.

3. The rejection under 35 U.S.C. 103 has been overcome by the amendment filed 6/9/2008.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 51-63 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of treatment of degenerative neurons that have been injured by ischemia or hypoxia, does not reasonably provide enablement for treatment of all neurons that are destined to die. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. Applicants show that they can heal neurons that have been injured by ischemia or hypoxia (example 9, pages 90-92). However, applicants are not enabled to heal all neurons that are destined to die.

> The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in Wands states, "Enablement is not precluded by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'" (*Wands*, 8

USPQ2sd 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations" (*Wands*, 8 USPQ2d 1404). Among these factors are: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Consideration of the relevant factors sufficient to establish a *prima facie* case for lack of enablement is set forth herein below:

(1) The nature of the invention and (2) the breadth of the claims:

The claims are drawn to a method of healing neurons that have been injured by ischemia or hypoxia. The compounds being used are compounds composed of a decahydropyrrolo[1,2-*a*]azocine ring core structure. Thus, the claims taken together with the specification imply that compounds of claims 46-50 can treat neurons that have been injured by ischemia or hypoxia.

(3) The state of the prior art and (4) the predictability or unpredictability of the art:

Immortality is not a possibility for animals currently. Vey ("Can we be immortal?", http://www.viewzone.com/aging.html, accessed August 29, 2008.) teaches:

So for humans to extend life we must do two things: first, eliminate the toxins in our environment that make short telomeres a "good thing" while finding a dietary or pharmaceutical method for increasing and preserving the length of our cells' telomeres. The twenty-first century may well be the era in which humans learn the secrets of eternal life, but it may also be a time to be reminded of the many dangers inherent in exploring these god-like abilities.

Vey teaches that immortality is not known right now, and that testing is still required. He also teaches that the only way to extend life is preserve the length of cells' telomers.

(5) The relative skill of those in the art:

Those of relative skill in the art are those with level of skill of the authors of the references cited to support the examiner's position. The relative skill of those in this art is MD's, PhD's, or those with advanced degrees and the requisite experience in treating injured neurons.

(6) The amount of direction or guidance presented and (7) the presence or absence of working examples:

The specification has provided guidance for guidance for treatment of neurons that have been injured by ischemia or hypoxia (example 9, pages 90-92 of the specification).

However, the specification does not provide guidance for treatment of all neurons destined to die.

(8) The quantity of experimentation necessary:

Considering the state of the art as discussed by the references above, particularly with regards to claims 51-63 and the high unpredictability in the art as evidenced therein, and the lack of guidance provided in the specification, one of ordinary skill in the art would be burdened with undue experimentation to practice the invention commensurate in the scope of the claims.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 53 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. What specific glutamate antagonists, AMPA antagonists, and anti-inflammatory agents are being used as additional agents?

Conclusion

8. Claims 46-50 appear free of the prior art of record.

9. The following is a statement of reasons for the indication of allowable subject matter: Harris et al. (*Organic Letters*, **2003**, *5(11)*, 1847-50, cited in IDS) teach compound 21 (page 1847). This compound fails to anticipate or render obvious because variable X of the instant claims in structure 21 is CH=CH-CH_2. Variable X in the instant set of claims can only be $(CH_2)_3$. In addition, the ring system of structure 21 reported by Harris et al. (decahydropyrrolo[1,2-*d*][1,4]diazocine) is not the same as the ring system of claims 46-50 (decahydropyrrolo[1,2-*a*]azocine). Another difference between the two structures is the group attached to the pyrrolo rings. In the instant application, a C(O)NH-CH(CO_2H)((CH_2)$_2$$CO_2$H) is attached to the pyrrolo ring. In structure 21 of Harris et al., a CO_2*t*-Bu group is attached to the pyrrole ring. Hence, compounds of claims 46-50 appear free of the closest prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NOBLE JARRELL whose telephone number is (571)272-9077. The examiner can normally be reached on M-F 7:30 A.M - 6:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Noble Jarrell/
Examiner, Art Unit 1624

/James O. Wilson/
Supervisory Patent Examiner, Art Unit 1624